



Prior Authorization Criteria  
**Growth Hormone**

All requests for Growth Hormone require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Growth Hormone Prior Authorization Criteria:

**Growth Hormone Agents addressed in this policy includes:** Norditropin™, Nutropin™/Nutropin AQ™, Genotropin™, Humatrope™, Omnitrope™, Zomacton™, Serostim™, Zorbtive™

Growth Hormone Agents

- The following Growth Hormone agents are formulary:
  - Norditropin™
- All other Growth Hormones agents are considered non-formulary and require documentation of failure with one of the formulary Growth Hormone agents in addition to meeting the criteria outlined below.

Coverage may be provided for all FDA approved indications. Certain diagnosis (es) may require additional criteria as listed below.

Products requested that correspond to appropriate FDA-approved indications are noted below:

<b>Indication</b>	<b>Product</b>
<b>Growth Failure in children</b>	Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Saizen, Tev-Tropin, Zomacton
<b>Growth Failure associated with Chronic Kidney Disease</b>	Nutropin/Nutropin AQ
<b>Growth Failure associated with Noonan Syndrome</b>	Norditropin
<b>Growth Failure associated with Prader-Will Syndrome</b>	Genotropin, Norditropin, Omnitrope
<b>Growth Failure in associated with SHOX deficiency</b>	Humatrope, Zomacton
<b>Growth failure or short stature associated with Turner syndrome</b>	Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Zomacton
<b>Growth hormone deficiency in adults</b>	Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Saizen, Zomacton

<b>Small for Gestational Age</b>	Genotropin, Humatrope, Norditropin, Omnitrope, Zomacton
<b>Idiopathic short stature</b>	Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Zomacton
<b>Cachexia associated with AIDS</b>	Serostim
<b>Short Bowel Syndrome</b>	Zorbtive

For all requests for Growth Hormone (Norditropin™, Nutropin™/Nutropin AQ™, Genotropin™, Humatrope™, Omnitrope™, Zomacton™, Serostim™, Zorbtive™) all of the following criteria must be met:

Coverage may be provided with a diagnosis of **Pediatric Growth Hormone Deficiency** and the following criteria is met:

- Prescribed medication is Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Saizen, Tev-Tropin, OR Zomacton.
- Member's height must be below the third percentile for their age and gender related height or more than 2 standard deviations below the mid-parental height percentile for gender and age
- Diagnosis must be confirmed by one of the following criteria:
  - Diagnosis confirmed by 2 provocative stimulation tests producing peak growth hormone concentrations <10 ng/mL
  - Member has a significant structural abnormality affecting the pituitary and 1 provocative stimulation test producing peak growth hormone concentrations < 10ng/ml.
    - No stimulation tests are needed in the setting of panhypopituitarism.
  - Member has panhypopituitarism (defined as at least 3 pituitary hormone deficiencies.
    - No stimulation tests are needed in the setting of panhypopituitarism.
  - Insulin growth factor-1 (IGF-1) a.k.a. somatomedin C, or IGF binding protein-3 (IGFBP-3) levels below normal range (reference range);
  - Radiographic documentation that bone age is > 2 standard deviations below the mean for chronological age;
  - Member produces two normal stimulation tests but has a height more than 2.25 standard deviations below the age related mean and a growth velocity below the 25<sup>th</sup> percentile for bone age;
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **Idiopathic Short Stature** and the following criteria is met:

- Prescribed medication is Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, or Zomacton
- Member's current height is below -2.25 standard deviations of the mean (ie, the 1.2<sup>nd</sup> percentile), and a predicted adult height that is below the normal range; this corresponds to an adult height of less than 63 inches for males, and less than 59 inches for females.
- Epiphyses is open
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **pediatric growth failure due to chronic renal failure** and the following criteria is met:

- Prescribed medication is Nutropin, or Nutropin AQ.
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- The member has not undergone a renal transplant.
- The member has not achieved adequate height after management of nutritional and metabolic abnormalities over at least 3 months.
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **growth failure in children born small for gestational age (SGA)**, and the following criteria is met:

- Prescribed medication is Genotropin, Humatrope, Norditropin, Omnitrope, or Zomacton.
- Diagnosis must be confirmed by the following:
  - Member's current height is more than 2 standard deviations below the mean for age and gender.
  - Member must meet ONE of the following requirements
    - Birth weight of less than 2500g at a gestational age of more than 37 weeks.
    - Weight, or length at birth is more than 2 standard deviations below the mean for gestational age.
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **pediatric growth failure due to Turner's syndrome** and the following criteria is met:

- Prescribed medications is Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, or Zomacton
- Member is female.
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- Diagnosis was confirmed by karyotyping.
- Epiphysis is open
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **pediatric growth failure due to Noonan's syndrome** and the following criteria is met:

- Prescribed medication is Norditropin
- Member's current height is more than 2 standard deviations below the mean for age and gender.
- Member has clinical features consistent with the typical presentation of this condition or diagnosis has been confirmed by genetic testing.
- Epiphyses are open.
- The medication is prescribed by a specialist such as an endocrinologist or neonatologist.
- The requested dose and frequency is within FDA-approved dosing recommendations

Coverage may be provided with a diagnosis of **Prader-Willi Syndrome** and the following criteria is met:

- Prescribed medications is Genotropin, Norditropin, or Omnitrope
- The medication is prescribed by a specialist such as an endocrinologist.
- Members under the age of 18 with ANY one of the following will not qualify for growth hormone:
  - Members who are severely obese (BMI more than or equal to 30).
  - Members with severe respiratory impairment.
  - Members with active history of upper airway obstruction or sleep apnea. (Members who are currently being treated with no symptoms do not meet this exclusion criteria).
- The medication is prescribed by a specialist such as an endocrinologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **Adult Growth Hormone Deficiency** and the following criteria is met:

- Prescribed medications is Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Zomactan
- Member is age 18 years and older, OR any aged with closed epiphyses.

- Member meets ONE of the following:
  - Member has a growth hormone stimulation test with peak growth hormone concentrations less than 5ng/mL as a result of ONE of the following:
    - Childhood onset growth hormone deficiency
    - Pituitary or Hypothalamic Disease
    - Surgery or Radiation Therapy
    - Trauma
  - Member has low IGF-1 and ONE of the following
    - Panhypopituitarism
    - Structural abnormality of the hypothalamus or pituitary gland
- The medication is prescribed by a specialist such as an endocrinologist.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **Cachexia or Wasting associated with AIDS** and the following criteria is met:

- Prescribed medications is Serostim.
- Member must have diagnosis of HIV infection.
- Member must have a history of trial and failure, contraindication, or intolerance to at least ONE of the following conventional treatments:
  - Megestrol
  - Predisone
  - Dronabinol
- Prescriber must attest to the following
  - Member must have involuntary weight loss of at least 10% from baseline premorbid weight or to a BMI <20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings.
  - Member must receive adequate caloric intake and nutritional counseling.
- The requested dose and frequency is within FDA-approved dosing recommendations.

Coverage may be provided with a diagnosis of **Short Bowel Syndrome** and the following criteria is met:

- Prescribed medications is Zorbtive.
- Member is age 18 years or older.
- Member has malabsorption from the small intestine that is marked by diarrhea, malnutrition, and steatorrhea and that results from resection of the small intestine.
- Member has a small intestine <200 cm in length.
- Member has one of the following:
  - Member has an intact stomach and duodenum as well as  $\geq 30\%$  of functioning colon with at least 15 cm of intact jejunum and/or ileum
  - Member has an intact stomach and duodenum as well as <30% functioning colon with at least 90 cm intact jejunum and/or ileum.
- Member must not have active malignancy.

- Member is receiving nutritional support.
- The requested dose and frequency is within FDA-approved dosing recommendations

Exclusion criteria:

- Acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; increased mortality has been reported with pharmacologic doses.
- Acute respiratory failure; increased mortality has been reported with pharmacologic doses.
- Active malignancy due to an increased risk of second neoplasm.
- Active proliferative or severe non-proliferative diabetic retinopathy.
- Closed epiphyses in pediatric patients.
- Progression or recurrence of underlying intracranial tumor.

**Initial Duration of Approval:**

- Pediatric human growth hormone deficiency, Idiopathic short stature, growth failure in children SGA, Turner's Syndrome, Noonan's Syndrome, Chronic renal failure
  - Initial Benefit: 12 months
- Prader-Willi Syndrome
  - Initial Benefit: 12 months
- Adult growth hormone deficiency syndrome
  - Initial Benefit: 6 months
- Cachexia or Wasting associated with AIDS
  - Initial Benefit: 12 week,
- Short Bowel Syndrome
  - Initial Benefit: 4 weeks

**Reauthorization criteria**

- Pediatric human growth hormone deficiency, Idiopathic short stature, growth failure in children due to SGA, Turner's Syndrome, Noonan's Syndrome, OR Chronic renal failure
  - Reauthorization: 12 months
    - Members currently is with open epiphyses
    - A growth velocity of  $\geq 2$  cm/yr. (Provider must provide current documented height, and previously documented height from 12 months ago.)
    - Attestation of the following:
      - Ongoing monitoring of IGF-1 level.
      - The member has not reached their expected final adult height.
- Prader-Willi Syndrome

- Reauthorization: 12 months
  - Presence of an improvement in linear growth or body composition (e.g., increase in lean body mass, lean/fat ratio, body weight, etc.).
- Adult growth hormone deficiency syndrome
  - Reauthorization: 6 months
    - Presence of clinical benefit (e.g., increase in total lean body mass, increase in IGF-1, or increase in exercise capacity) and attestation of ongoing monitoring of IGF-1 level.
- Cachexia or Wasting associated with AIDS
  - Reauthorization: Up to 36 weeks
    - Presence of weight stabilization or weight gain. (Provider must provide pretreatment weight, and current weight.)
    - Duration of treatment will not exceed 48 weeks.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

**Growth Hormone**

(Norditropin<sup>TM\*\*</sup>, Nutropin<sup>TM</sup>/Nutropin AQ<sup>TM</sup>, Genoptropin<sup>TM</sup>, Humatrope<sup>TM</sup>, Omnitrope<sup>TM</sup>, Zomacton<sup>TM</sup>, Serostim<sup>TM</sup>, Zorbtive<sup>TM</sup>)

**PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health Pharmacy Services. **FAX:** (855) 476-4158

If needed, you may call to speak to a Pharmacy Services Representative.  
**PHONE:** (844) 325-6253 Monday through Friday 8:00am to 6:00pm EST

\*\*Please note that Norditropin is on formulary

**PROVIDER INFORMATION**

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

**MEMBER INFORMATION**

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

**REQUESTED DRUG INFORMATION**

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date Medication Initiated:

**Billing Information**

This medication will be billed:  at a pharmacy **OR**  
 medically (if medically please provide a  
JCODE: \_\_\_\_\_

Place of Service:  Hospital  Provider's office  Member's home  Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

**MEDICAL HISTORY (Complete for ALL requests)**

**Diagnosis:**

- Pediatric Growth Hormone Deficiency
- Idiopathic Short Stature
- Pediatric Growth Failure Due to Chronic Kidney Disease
- Growth Failure in Children Born Small for Gestational Age (SGA)
- Pediatric Growth Failure Due to Turner's Syndrome
- Pediatric Growth Failure Due to Noonan's Syndrome
- Prader-Willi Syndrome
- Adult Growth Hormone Deficiency



Cachexia or Wasting Associated with AIDS

Short Bowel Syndrome

Other: \_\_\_\_\_

**For all members/diagnoses:**

Does the member have an acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma?  Yes  No

Does the member have acute respiratory failure?  Yes  No

Does the member have an active malignancy?  Yes  No

Does the member have active proliferative or severe non-proliferative diabetic retinopathy?  Yes  No

Is the member a pediatric patient with closed epiphyses?  Yes  No

Does the member have progression of or recurrence of underlying intracranial tumor?  Yes  No

**For Pediatric Growth Hormone Deficiency:**

Is the prescribed medication: Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Saizen, Tev-Tropin, OR Zomacton?  Yes  No

Is the member's height below the third percentile for their age and gender related height OR more than two standard deviations below the mid-parental height percentile for gender and age?  Yes  No

Does the member have a diagnosis of failure to grow **including** (one of the following criteria):

- Confirmation by 2 provocative stimulation tests producing peak growth hormone concentrations < 10 ng/mL?  Yes  No
- Significant structural abnormality affecting the pituitary and 1 provocative stimulation test producing peak growth hormone concentrations < 10 ng/mL?  Yes  No
- Panhypopituitarism defined by at least 3 pituitary hormone deficiencies (no stimulation tests needed)?  Yes  No
- Insulin growth factor-1 (IGF-1) [aka somatomedin C or IGF binding protein-3 (IGFBP-3)] levels below normal range (reference range)?  Yes  No
- Radiographic documentation that bone age is > 2 standard deviations below the mean for chronological age?  Yes  No
- Two normal stimulation tests but has a height more than 2.25 standard deviations below the age related mean and a growth velocity below the 25<sup>th</sup> percentile for bone age?  Yes  No

Is the medication prescribed by or in association with an endocrinologist or neonatologist?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  Yes  No

**For Idiopathic Short Stature:**

Is the prescribed medication: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, or Omnitrope?  Yes  No

Is the member's current height below -2.25 standard deviations of the mean (the 1.2<sup>nd</sup> percentile)?  Yes  No

Does the member have a predicted adult height that is below the normal range (meaning an adult height less than 63 inches for males and less than 59 inches for females)?  Yes  No

Does the member have open epiphyses?  Yes  No

Is the medication being prescribed by an endocrinologist or neonatologist?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  Yes  No

**For Pediatric Growth Failure Due to Chronic Kidney Disease:**

Is the prescribed medication: Nutropin, or Nutropin AQ?  Yes  No  
 Is the member's current height more than 2 standard deviations below the mean for age and gender?  Yes  No  
 Has the member undergone a renal transplant?  Yes  No  
 Has the member failed to achieve adequate height after management of nutritional and metabolic abnormalities over at least 3 months?  Yes  No  
 Is the medication being prescribed by an endocrinologist or neonatologist?  Yes  No  
 Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  Yes  No

**For Growth Failure in Children Born Small for Gestational Age (SGA):**

Is the prescribed medication: Genotropin, Humatrope, Norditropin, or Omnitrope?  Yes  No  
 Does the member have a diagnosis confirmed by:

- Current height more than 2 standard deviations below the mean for age and gender?  Yes  No
- Birth weight of less than 2500 g at gestational age of more than 37 weeks?  Yes  No
- Weight or length at birth is more than 2 standard deviations below the mean for gestational age?  Yes  No

Is the member less than 2 years of age?  Yes  No  
 Is the medication being prescribed by an endocrinologist or neonatologist?  Yes  No  
 Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  Yes  No

**For Pediatric Growth Failure Due to Turner's Syndrome:**

Is the prescribed medication: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, or Omnitrope?  Yes  No  
 Is the member female?  Yes  No  
 Is the member's current height more than 2 standard deviations below the mean for age and gender?  Yes  No  
 Was the diagnosis confirmed by karyotyping?  Yes  No  
 Does the member have open epiphysis?  Yes  No  
 Is the medication being prescribed by an endocrinologist or neonatologist?  Yes  No  
 Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  Yes  No

**For Pediatric Growth Failure Due to Noonan's Syndrome:**

Is the prescribed medication Norditropin?  Yes  No  
 Is the member's current height more than 2 standard deviations below the mean for age and gender?  Yes  No  
 Does the member have clinical features consistent with the typical presentation of this condition?  Yes  No  
 Has the diagnosis been confirmed by genetic testing?  Yes  No  
 Does the member have open epiphyses?  Yes  No  
 Is the medication being prescribed by an endocrinologist or neonatologist?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  
 Yes  No

**For Prader-Willi Syndrome:**

Is the prescribed medication: Genotropin, Norditropin, or Omnitrope?  Yes  No

Is the medication being prescribed by a specialist such as an endocrinologist?  Yes  No

Is the member under the age of 18?  Yes  No

Does the member have any of the following?:

- Severe obesity (BMI more than or equal to 30)?  Yes  No
- Severe respiratory impairment?  Yes  No
- A history of upper airway obstruction or sleep apnea?  Yes  No

Is the medication being prescribed by a specialist such as an endocrinologist?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  
 Yes  No

**For Adult Growth Hormone Deficiency:**

Is the prescribed medication: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Zomactan?  Yes  No

Is the member's age 18 years or older?  Yes  No

Does the member have closed epiphyses?  Yes  No

Has the member undergone a growth hormone stimulation test with peak growth hormone concentrations less than 5 ng/mL resulting from:

- Childhood onset growth hormone deficiency?  Yes  No
- Pituitary or hypothalamic disease?  Yes  No
- Surgery or radiation therapy?  Yes  No
- Trauma?  Yes  No

Is the medication being prescribed by a specialist such as an endocrinologist?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  
 Yes  No

**For Cachexia or Wasting Associated with AIDS:**

Is the prescribed medication Serostim?  Yes  No

Does the member have a diagnosis of HIV infection?  Yes  No

Has the member tried and failed **or** have a contraindication or intolerance to:

- Megestrol?  Yes  No
- Prednisone?  Yes  No
- Dronabinol?  Yes  No

Has the member had an involuntary weight loss of at least 10% from baseline premorbid weight or to a BMI <20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings?

Yes  No

Is the member receiving adequate caloric intake and nutritional counseling?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  
 Yes  No

**For Short Bowel Syndrome:**

Is the prescribed medication Zorbtive?  Yes  No

Is the member's age 18 years or older?  Yes  No

Does the member have malabsorption from the small intestines that is marked by diarrhea, mal-nutrition, and steatorrhea that results from resection of the small intestine?  Yes  No

Does the member have a small intestine <200 cm in length?  Yes  No

Does the member have an intact stomach and duodenum as well as  $\geq 30\%$  of functioning colon with at least 15 cm of intact jejunum and/or ileum?  Yes  No

Does the member have an intact stomach and duodenum as well as <30% functioning colon with at least 90 cm intact jejunum and/or ileum?  Yes  No

Does the member have an active malignancy?  Yes  No

Is the member receiving nutritional support?  Yes  No

Is the dose and frequency of the medication being requested within FDA-approved dosing recommendations?  
 Yes  No

**CURRENT or PREVIOUS THERAPY**

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

**Prescribing Provider Signature**

**Date**